Commonwealth of Virginia Department of General Services Division of Consolidated Laboratory Services Richmond, Virginia

Drinking Water Onsite Assessment Corrective Plan Form

LAB NAME:	A, B & C Water Laboratory	LAB ID: 0	00999	SITE VISIT DATE(S):	1/14-15/2020	
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Corrective action must be completed and supporting documentation submitted within 60 days of receiving the assessment report.

Finding or Issue #	Laboratory's Corrective Action Plan – include sufficient detail to communicate	14 O - 1 14 - D O I O 4	DCLS LABORATORY CERTIFICATION USE		
	that the plan has addressed the finding observed in a manner to prevent recurrence ¹	Items Submitted to DCLS to Demonstrate Completion ²	Plan Approved [Y/N]	Documents Received [Date]	Documents Accepted [Date]
B.1	Purchase known positive and negative culture controls for testing tryptic soy broth.	Purchase order/packing list			
B.2	Add a log sheet to the calibration notebook book for tracking the calibration history of the IR thermometer, and calibrate the IR thermometer immediately.	Copy of completed log sheet showing calibration of the IR thermometer Copy of calibration status label			
	Revise calibration and maintenance schedule to include calibration requirements for the IR thermometer.	applied to the IR thermometer Copy of revised calibration and maintenance schedule			
C.1	Discard all Colisure media packets that have been exposed to light. Designate a storage location protected from light.	Photo of designated storage location			
	Post a job aid at the bench to remind analysts to get out only the number of packets needed for analyses.	Copy of job aid			

¹ Include descriptions of updates to Quality Manual, SOPs, bench sheets, training records, etc. as relevant to demonstrate <u>full implementation</u> of the corrective action plan. Typical corrective actions require updates to POLICY/PROCEDURE + PRACTICE, accompanied by STAFF TRAINING, for full implementation.

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² Documentation demonstrating that the corrective action plan has been implemented is required for all drinking water laboratory assessments.

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or Issue #	that the plan has addressed the finding observed in a manner to prevent recurrence ¹	Items Submitted to DCLS to Demonstrate Completion ²	Plan Approved [Y/N]	Documents Received [Date]	Documents Accepted [Date]
D.1	Purchase 0.1 N H ₂ SO ₄ titrant for use with high alkalinity samples.	Copy of purchase order and packing list			
	Revise SOP to state when it is appropriate to use the stronger titrant.	Copy of revised SOP			
D2	Purchase larger sterile containers for mixing samples that do not have sufficient headspace for mixing in the 100 mL bottle.	Copy of packing list for purchase of larger containers			
F.1 F.2 F.3	 Revise Quality Manual to ensure that the types and frequencies of calibration of all instruments and equipment are addressed or referenced; the schedule of system audits includes external audits as well as internal audits; the Quality Manual includes a discussion of data integrity and laboratory ethics. 	Copy of revised section(s) of the Quality Manual			
All	Hold training sessions for analysts prior to the effective dates of the revised Quality Manual and SOPs as well as implementation of new/revised bench sheets and logs.	Copies of training agendas and attendance sheets.			

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FINDINGS

- B.1 Each new lot of prepared commercial medium should be checked before use for sterility and with a positive culture control. [EPA *Manual*, Ch. V, §5.1.6.4] At the time of the on-site inspection, each lot of tryptic soy broth was inoculated with an unknown environmental sample instead of a known positive culture control.
- B.2 When an infrared [IR] detection device is used to measure the temperature of samples, the device should be verified at least every six months using a NIST certified thermometer over the full temperature range that the IR thermometer will be used (EPA Manual, Chapter 4, §7.1.5). The IR temperature measurement device in use in the chemistry laboratory at the time of the inspection had not been verified against a NIST certified thermometer.
- C. [Colisure] media must be protected from light [EPA *Manual*, Ch. V, §5.3.1.2.2]. At the time of the on-site inspection, packets of Colisure reagent were stored uncovered on the laboratory bench.
- D.1 "Do not filter, dilute, concentrate, or alter sample" [SM2320 B.1.c-2011]. At the time of the on-site assessment, the laboratory diluted samples that required more than 10 mL of 0.02 N H₂SO₄ titrant.
- D.2 At least 100 mL of sample must be collected, allowing at least a 1-inch air space to facilitate mixing of the sample by shaking If a sample bottle is filled too full to allow for proper mixing, do not pour off and discard a portion of the sample. Rather, pour the entire sample into a larger sterile container, mix properly, and proceed with the analysis [EPA Manual, Chapter V §6.2.1]. At the time of the assessment, the laboratory did not demonstrate that larger sterile containers were available for mixing samples when over-filled 100 mL sample containers are received.
- F.1 Specify type of calibration used for each method and frequency of use [EPA Manual Chapter III §11.6]. The Quality Manual in effect at the time of the assessment did not contain or reference an SOP containing the process for verifying calibration of the autoclave timer.
- F.2 List schedules of internal and external system and data quality audits and inter laboratory comparisons (may reference SOP). [EPA Manual, Chapter 3 §11.10] The laboratory Quality Manual in effect at the time of the assessment did not contain or reference schedules of external system and data quality audits.
- F.3 Laboratories are encouraged to have an ethics policy and implement a fraud detection and deterrence policy/program [Supplement 1 to the Fifth Edition of the EPA *Manual*, Ch. III New Section]. **The Quality Assurance Plan in effect at the time of the inspection did not contain or reference a Laboratory Ethics and Fraud Detection/Deterrence policy.**
 - NOTE: EPA Region III has communicated this policy as a key standard practice for laboratories operating in EPA Region III.

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